UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re Bristol-Myers Squibb Company CVR Securities Litigation	No. 1:21-CV-08255-JMF ORAL ARGUMENT REQUESTED

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE SECOND AMENDED CLASS ACTION COMPLAINT

COHEN MILSTEIN SELLERS & TOLL PLLC
Michael B. Eisenkraft
Laura H. Posner
Benjamin F. Jackson
88 Pine Street
14th Floor
New York, NY 10005
Tel. (212) 838-7797
meisenkraft@cohenmilstein.com
lposner@cohenmilstein.com
bjackson@cohenmilstein.com

Steven J. Toll (*pro hac vice*)
Brendan Schneiderman (*pro hac vice*)
1100 New York Avenue, N.W
East Tower, STE. 500
Washington, DC 20005
Tel. (202) 408-4600
stoll@cohenmilstein.com
bschneiderman@cohenmilstein.com

Lead Counsel for Lead Plaintiff, Ehab Khalil, and the Proposed Class

(Additional counsel on signature page.)

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PRELIMINARY STATEMENT

On March 1, 2023, this Court dismissed Plaintiffs' Amended Complaint on the basis that Plaintiffs' Exchange Act claims did not adequately allege scienter (the "Order") (ECF No. 110). However, the Court permitted Plaintiffs to amend their Amended Complaint to address the Court's concerns and "nudge [its] claims across the line from conceivable to plausible[.]" *Id*. at 6. The Second Amended Complaint ("SAC") (ECF No. 115) does exactly that.

First, the SAC features substantial new allegations demonstrating Bristol's corporate structure ensured that its leadership, including the Individual Defendants, knew about the Liso-cel submission and approval failures. Namely, Plaintiffs show that the Company's Science & Technology and Integration Committees – on which Defendant Caforio sat and which reported directly to Bristol's Board of Directors – provided Bristol's executives with regular updates regarding the FDA-related failures. SAC ¶¶ 37-40, 178-82. The SAC also describes internal FDA documents demonstrating extensive direct communication between Bristol's senior personnel, including Defendant Caforio, and the FDA regarding the Company's Liso-cel submissions and approval process failures. *See* SAC ¶ 41 (up to forty Bristol employees cc'ed on letters with FDA and dozens attended Center for Biologics Evaluation and Research ("CBER") meetings); SAC ¶ 46 (VP of Cell Therapy Development and Operations Quality was present for FDA "closing meetings"); SAC ¶ 175 (FDA Establishment Inspection Reports addressed to Caforio personally).

Regarding Bristol's failures with respect to the inspections of its two Liso-cel facilities, Plaintiffs' FDA Biologics Expert now identifies specifically who at Bristol was involved in the Form 483 responses, SAC ¶ 49, how implausible Bristol's failure to adequately prepare the sites for inspection was, SAC ¶¶ 146, and that Bristol submitted clearly deficient "fluff" in its responses to the FDA's Form 483s. SAC ¶¶ 48, 196. The SAC further alleges that "numerous Vice Presidents and Directors of Quality and Manufacturing Groups at Bristol" – now identified by

name as identified in internal FDA communications – "were fully aware of the many deficiencies that existed and voiced no objections to the deficiency findings of the FDA Investigators," thus conceding they were accurate. SAC ¶ 5, n.2.

The SAC also includes new allegations from Plaintiffs' FDA Biologics Expert regarding how Bristol's senior personnel was involved in the creation, review, and submission of the "most important section of the [Biologic License Application ("BLA")]," the Chemistry, Manufacturing and Controls ("CMC"). SAC ¶¶ 26, 27. 29, 32. The SAC also highlights that Bristol's leaders – including Defendants CEO Caforio and Chief Medical Officer Hirawat – repeatedly provided public commentary on the approval of Liso-cel, such that they knew or were reckless in not knowing that it was highly unlikely that Liso-cel would be approved by the Milestone deadline. Indeed, as the SAC now explains, because the Celgene merger was one of the largest mergers in industry history and "all eyes" were on it, Bristol's leadership, including Defendant Caforio, were intimately involved in Bristol's integration of and FDA approval for Celgene's revolutionary therapies. SAC ¶¶ 10-14, 19, 92-94, 105-114, 116-120.

In addition, the SAC includes allegations from new Confidential Witnesses ("CWs"), including CW #9, who stated that Defendant CEO Caforio and his executive co-defendants would have been aware of underlying issues regarding the FDA approval process for Liso-cel, SAC ¶¶ 47, 177, and CW #10, who stated that Caforio "should have been apprised" of the Liso-cel approval situation, SAC ¶¶ 47, 172 n.11. The SAC also includes allegations from CW #11, who alleges that the approval of his vacation on December 18, 2020, would not have happened if there were "any chance" of Liso-cel's being approved by the Milestone deadline. SAC ¶ 165.

Finally, the SAC shows that the missed Milestone date cannot be blamed on the COVID-19 pandemic or mere "mismanagement." In addition to the other new allegations described above,

the SAC includes a statistical analysis, conducted by Plaintiffs' FDA Biologics Expert, of the approval time of Liso-cel compared with similar drugs approved during COVID-19 by the FDA, which shows that the approval of Liso-cel was statistically anomalous. SAC ¶¶ 52, 133-34, 203-06, 289. The SAC also features allegations from that Expert and CW #10 that the delay in approval of Liso-cel cannot be blamed on COVID-19 alone, because even after the FDA inspected the Lonza facility, it still did not pass inspection. SAC ¶ 194-96. These additional factual allegations show that there was "more than a sheer possibility" that Defendants violated the federal securities laws.

FACTUAL ALLEGATIONS

Bristol is one of the world's largest pharmaceutical companies. SAC ¶ 4. Defendants Giovanni Caforio (Chief Executive Officer or CEO) and Samit Hirawat (Executive Vice President and Chief Medical Officer) have long been two of its most senior executives. SAC ¶¶ 65-66. In 2018, Bristol offered to buy Celgene, mainly to acquire its five drugs slated for imminent U.S. Food and Drug Administration ("FDA") approval. SAC ¶¶ 15-16. The two ultimately agreed on a deal whereby Celgene's shareholders would receive Contingent Value Rights ("CVRs")[1] as partial consideration for the merger, SAC ¶ 20, but only if ***all three*** of Celgene's pipeline drugs (the "Milestone Drugs") were approved prior to specific milestone dates, SAC ¶ 112. For Liso-cel, that date was December 31, 2020. SAC ¶ 112. Bristol repeatedly represented that it would use "diligent efforts" to ensure the Milestone Drugs' approval by the milestone dates. SAC ¶ 24.

After the merger closed on November 20, 2019, Bristol took over the Liso-cel FDA approval process. SAC ¶¶ 25-26. At the time, FDA's target approval date[2] for Liso-cel was August 17, 2020—***four and a half months*** before the Liso-cel milestone date. SAC ¶ 134. But a

[1] A CVR is a security payable upon the occurrence of a specific future event. SAC ¶ 1.

[2] The target date is the FDA's Prescription Drug User Fee Act ("PDUFA") target approval deadline (which is why it is also called the "PDUFA date"). SAC ¶ 34.

litany of Bristol-inflicted delays pushed back Liso-cel's approval until thirty-six days after the Liso-cel Milestone date, just enough time for Bristol to avoid paying billions to investors, but still get the benefit of Liso-cel revenue moving forward. SAC ¶ 183. Those inexplicable errors included: a month-long pause in the BLA submissions for Liso-cel between Bristol's taking over the FDA application process and its submitting the CMC module on December 18, 2019, SAC ¶¶ 27, 131; the omission of critical data required by the FDA in every single CMC and ***which Bristol does not dispute it had in its possession*** at the time of its submission, SAC ¶ 135; a three-week delay in submission of the proper data once the FDA notified Bristol of its omission, SAC ¶ 138; a 90-day PDUFA deadline extension as a result of that submission because it constituted a "Major Amendment", SAC ¶ 139-40; the rescheduling of the inspections of Liso-cel facilities from June 2020 to October and December 2020, SAC ¶ 142; failed FDA inspections of the Liso-cel facilities as a result of basic, rudimentary issues, not COVID-19, resulting in the issuance of Form 483s, SAC ¶¶ 145-50; and delays in responding to said Form 483s, SAC ¶¶ 151, 166. After the delays caused by Bristol's series of highly unusual "errors" prevented approval of Liso-cel before the December 31, 2020 deadline, the FDA finally approved Liso-cel's BLA on February 5, 2021—36 days after the Milestone date lapsed, depriving the CVR holders of $6.4 billion. SAC ¶¶ 183.

As they slow-rolled Liso-cel's approval, Defendants repeatedly made materially false and misleading statements concerning the "***diligent efforts***" Bristol was purportedly making to secure Liso-cel's approval by the milestone date, the likelihood of securing approval by that date, and the purported value of the CVRs. SAC ¶¶ 232-79. But, in reality, the only thing "diligent" about Bristol's "efforts" was that it was doing everything in its power to ensure that it would miss the milestone deadline just enough to avoid paying investors billions.

LEGAL STANDARDS FOR A MOTION TO DISMISS

"In reviewing a motion to dismiss pursuant to Rule 12(b)(6), a court must accept the factual

allegations set forth in the complaint as true and draw all reasonable inferences in favor of the plaintiff." Order at 3.

"The Second Circuit and district courts in this circuit routinely rely on expert and statistical analyses contained in pleadings." *In re Platinum & Palladium Antitrust Litig.*, No. 14-CV-9391, 2017 WL 1169626, at *13 n.9 (S.D.N.Y. Mar. 28, 2017) (collecting cases).[3] The complaint may also "rely on confidential sources," including confidential witnesses or confidential experts "described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged." *In re Ambac Fin. Grp., Inc. Sec. Litig.*, 693 F. Supp. 2d at 283 (quoting *Novak v. Kasaks*, 216 F.3d 300, 314 (2d Cir. 2000)); *see also Sjunde AP-Fonden v. Gen. Elec. Co.*, 417 F. Supp. 3d 379, 409, 413–14 (S.D.N.Y. 2019) (Furman, J.) (upholding claims based on assertions by former employees).

ARGUMENT

I. THE AMENDED COMPLAINT ADDRESSES THE DEFICIENCIES

[3] Defendants reiterate that Plaintiffs' use of an FDA Biologics Expert is "inadmissible," Def. Br. ("DB") (ECF No. 119) 2, and not entitled to a "presumption of truthfulness." DB 13. As Plaintiffs previously explained, this claim is erroneous. "The Second Circuit and district courts in this circuit routinely rely on expert and statistical analyses contained in pleadings." *In re Platinum*, 2017 WL 1169626, at *13 n.9 (collecting cases)*; see also In re Platinum & Palladium Antitrust Litig.* 61 F.4th 242 (2d Cir. 2023) (deciding appeal without questioning use of expert). Defendants also attack Plaintiffs' use of the Expert as "hindsight criticisms [from someone] who has no apparent personal knowledge of relevant facts." DB 9. But the Biologics Expert is an expert, not a percipient witness, and complaints in this District may rely on confidential ***experts*** to help establish scienter. *See In re Ambac Fin. Grp., Inc. Sec. Litig.*, 693 F. Supp. 2d 241, 283 (S.D.N.Y. 2010) (quoting *Novak v. Kasaks*, 216 F.3d 300, 314 (2d Cir. 2000)).

IDENTIFIED BY THIS COURT.

In granting leave for Plaintiffs to amend certain of their claims,[4] the Court gave Plaintiffs the opportunity to supplement their pleadings with additional information, to "nudge [their] claims across the line from conceivable to plausible[.]" Order at 6 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Plaintiffs' SAC does just that.

A. The Amended Complaint Alleges a Strong Inference of Scienter.

To sufficiently allege scienter, "a complaint must, with respect to each defendant and 'with respect to each act or omission alleged to [constitute securities fraud], state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" Order at 7. The inquiry is whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard. *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 310 (2007). The inference of scienter need not be irrefutable, *i.e.,* "of the 'smoking-gun' genre or even the most plausible of inferences," *id.* at 324, but "if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged," Order at 8, the complaint must survive. "In this Circuit, a plaintiff may satisfy the scienter pleading requirement in either of two ways: by alleging facts (1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." Order at 4.[5] The SAC does both.

[4] This refers to Plaintiffs' claims arising under Section 10(b) and Section 20(a) of the Exchange Act. Plaintiffs have re-pled the other claims, dismissed by this Court without leave to amend, only to preserve them for potential appeal if necessary.

[5] These two provisions are written disjunctively, and recent binding precedent has not held that, where there is no evidence of motive, the strength of the circumstantial allegations of scienter must be greater. *See, e.g.*, *Tellabs*, 551 U.S. 308 (making no mention of a higher standard for cases

1. The Amended Complaint Adequately Alleges Strong Circumstantial Evidence of Conscious Misbehavior or Recklessness.

The SAC alleges sufficient facts, considered collectively as they must be, to "support an inference that the Executive Defendants and/or Bristol itself knew (or should have known) of the alleged missteps" in the FDA approval process. Order at 12.

First, Plaintiffs plead with particularity – relying on internal FDA documents – that numerous senior Bristol executives, including Defendants Caforio, Arduini, Emmens, Paliwal, and Vousden, were in ***direct communication*** with the FDA regarding the Liso-cel approval process, and knew through both Bristol's FDA submissions and the direct communications from the FDA in response thereto, that Bristol had submitted a wholly inadequate BLA, that the FDA had issued a Major Amendment determination, and, through the Form 483s and Bristol's inadequate responses thereto, that the Liso-cel facilities were woefully and inexplicably ill-prepared for FDA inspection. SAC ¶ 41. Indeed, the communication between the FDA and Bristol was extensive during the approval process, with letters from the FDA being sent to as many as *forty* Bristol employees, and there were multiple meetings between CBER and Bristol, attended by dozens of Bristol employees throughout the relevant time. *Id.* Bristol's VP of Cell Therapy Development and Operations Quality, Maria Brown, was even present for the "closing meeting" with the FDA, wherein she was notified of the inspection failures at Bristol's facilities. SAC ¶ 46. Bristol, through its most senior executives, was thus kept fully aware of its inadequate FDA submissions

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lacking allegations of motive); *Moab Partners, L.P. v. Macquarie Infrastructure Corp.*, No. 21-CV-2524, 2022 WL 17815767, at *4 (2d Cir. Dec. 20, 2022) (noting both avenues for scienter, without noting any sliding scale weighting); *Set Cap. LLC v. Credit Suisse Grp. AG*, 996 F.3d 64, 78 (2d Cir. 2021) (same); *Employees' Retirement System of Gov't of the Virgin Islands v. Blanford*, 794 F.3d 297, 306 (2d Cir. 2015) (same) (citing *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007))). Regardless, as set forth in Section A(2), Plaintiffs do sufficiently allege Defendants' motive and, even if they did not, Plaintiffs' allegations regarding conscious misbehavior or recklessness still clear the higher bar.

and facility inspections failures, which made clear that Liso-cel was highly unlikely to be approved by the deadline and that Bristol's efforts were anything but "diligent." As the Court noted in its Order, claims based on recklessness are sufficient when plaintiffs have alleged defendants' knowledge of facts *or* access to information contradicting their public statements. Order at 9 (citing *Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000)); *In re Alibaba Grp. Holding Ltd. Sec. Litig.*, No. 20-CV-9568, 2023 WL 2601472, at *13 (S.D.N.Y. Mar. 22, 2023) (finding a strong inference of scienter because defendants "would have known or had access to facts" in certain documents which were "contrary to its representations to investors"); *Set Cap. LLC*, 996 F.3d at 79 (that defendants "knew facts or had access to information suggesting that their public statements were not accurate" supports an inference of scienter).

Second, Defendants served on Board-level committees that reported directly to the entire Bristol Board and were specifically tasked with overseeing the integration of the Celgene drugs, including Liso-cel, within Bristol. Defendants' service on these committee necessarily required knowledge regarding where Liso-cel was in the FDA approval process, what information had been submitted to the FDA and any feedback received from the FDA regarding Bristol's submissions. For example, Bristol's Integration Committee – on which Defendants Caforio, Arduini, Emmens, Paliwal, and Vousden sat – was responsible for overseeing "***all aspects of the Celgene integration***" including "***integrating Celgene's pipeline and monitoring portfolio prioritization and execution***" of that pipeline, as well as providing "***regular reports to the Board on the progress of the Merger integration***[.]" SAC ¶ 178. That Committee met *nine times* between 2019 and 2020. Similarly, Bristol's Science & Technology Committee – on which Defendants Sato, Arduini, Emmens, and Vousden all sat – was responsible for overseeing Bristol's "pipeline of new pharmaceuticals." SAC ¶ 178. Among its responsibilities were "***overseeing*** and ***regularly reviewing*** Bristol's

pipeline," and "advising Bristol's Board [including Defendant Caforio] on the Company's progress in achieving near-term and long-term [research and development] goals[.]" SAC ¶ 178. That Committee met *twenty times* between 2019 and 2020. The newly added allegations in the SAC regarding these Committees and the extensive involvement of high-level officers in the approval process and communicating with the FDA over Liso-cel demonstrates the knowledge the Company had and/or the access it had to information contradicting its public statements.

Courts regularly find that corporate committee membership supports an inference of scienter regarding the information within that committee's jurisdiction. *See, e.g.*, *In re Peabody Energy Corp. Sec. Litig.*, No. 20-CV-8024, 2022 WL 671222, at *22 (S.D.N.Y. Mar. 7, 2022) (imputing scienter of smoke and fire at mining site because corporate defendant had assembled a task force regarding the site); *Venkataraman v. Kandi Techs. Grp., Inc.*, No. 20-CV-8082, 2022 WL 4225562, at *7 (S.D.N.Y. Sept. 13, 2022) (imputing scienter to individual defendants because of their presence at audit committee meeting); *In re Longwei Petroleum Inv. Holding Ltd. Sec. Litig.*, No. 13-CV-214, 2014 WL 285103, at *5 (S.D.N.Y. Jan. 27, 2014) (scienter sufficiently alleged against audit committee members because committee failed to act in response to red flags); *In re Comverse Tech., Inc. Sec. Litig.*, 543 F. Supp. 2d 134, 144–45 (E.D.N.Y. 2008) (imputing scienter in part based on audit committee members' "likely experience and knowledge").[6]

Third, Bristol's former employees confirm Defendants were regularly updated and informed during the Liso-cel approval process. CW #9, who contributed updates to senior

[6] Defendants ignore the significance of these Committees – the word "Committee" appears nowhere in their brief – and instead argue that Plaintiffs offer nothing but "generalized allegations concerning the management of board responsibilities of the individual defendants." DB 21. But six Individual Defendants, including Defendant Caforio, sat on these Committees, which met a total of twenty-nine times during the relevant time, and whose jurisdictions covered exactly the subject matter at issue here. And the information discussed and obtained in both Committees was so important it was reported to the entire Bristol Board, including Caforio.

management at the relevant time, confirmed that senior leadership, including Defendant Caforio, were "aware of the underlying issues regarding the FDA approval process for Liso-cel," because they "were included as part of the [FDA] communication updates," and with a "high degree of frequency" were provided with "Liso-cel program updates." SAC ¶ 177. CW #9 also confirmed Bristol management gave "priority attention" to Liso-cel's approval. *Id.* CW #10, an executive in Bristol's quality department, confirmed Caforio "should have been apprised of the situation" and "should have known about all such FDA communications." SAC ¶ 47.[7] Multiple confidential witnesses' alleging defendants' knowledge of a fact supports a strong inference of scienter. *See, e.g.*, *Freudenberg v. E*Trade Financial Corp.*, 712 F. Supp. 2d 171, 197 (S.D.N.Y. 2010) (corroboration from multiple confidential witnesses "supports an inference of a scienter"); *Galestan v. OneMain Holdings, Inc.*, 348 F. Supp. 3d 282, 301 (S.D.N.Y. 2018) (same). Accordingly, Defendants knew, or at least were reckless in not knowing, of the Company's repeated intentional or reckless missteps in the FDA approval process, and that the Company was not "on track" for or using "diligent efforts" to get Liso-Cel approved before the deadline.[8]

Relatedly, the SAC includes allegations from the FDA Biologics Expert which support an inference that Defendants knew or should have known about Liso-cel's obvious and inexplicable FDA submission and inspection failures because the mistakes were so glaring and extraordinary

[7] Regarding the testimony of CW's #9 and #10, Defendants argue only that "BMS disclosed developments with the relevant [FDA] applications as they occurred." DB 21. But, even if true (which, for the reasons discussed herein, *see infra* at 21-25, it is not), Defendants still falsely told investors throughout the relevant time that they remained "on track" for and were using "diligent efforts" to meet the Milestone deadline despite knowing, from at least as early as the deficient FDA submission in December 2019, that the Milestone deadline was highly unlikely to be met and that Bristol's efforts were far from "diligent."

[8] The statements by CWs #9 and #10 differ dramatically from the confidential witness statements in *Glaser v. The9, Ltd. See* 772 F. Supp. 2d 573, 594 (S.D.N.Y. 2011). In *Glaser*, which involved alleged fraud due to a licensee's overstating of the likelihood of the renewal of a profitable license, the confidential witnesses made allegations in no way related to the license at issue.

for a company with Bristol's expertise. *See, e.g.*, SAC ¶ 27 (because the CMC "is the most important section of the BLA," "a pharmaceutical giant like Bristol normally would have filed [it] immediately following the closing of the Merger"); SAC ¶ 29 ("any pharmaceutical executive who worked on submitting biologics… would have known that it was incredibly important for the BLA application to contain all the required data and information, not simply summaries"); SAC ¶ 49 ("No one, much less an experienced drug company like Bristol, would ever have omitted such key information"); SAC ¶ 138 ("[The] 23-day delay in providing the missing [CMC data] to the FDA was[] 'highly unusual,' because a company at this stage of the BLA process would almost certainly have already had the necessary data and be[en] able to immediately submit it."); SAC ¶ 147-48, 151-52, 162-63 (noting the inspection-related errors "should not have been made" for "an experienced company like Bristol with licensed biologic products").

Fourth, Bristol's executives regularly spoke in detail about the state of the Liso-cel approval process. For example, in the weeks leading up to the Merger, Defendants Caforio and Hirawat emphasized to investors that approval of Liso-cel was on track and that executives and Board members were committed to achieving timely approval of the drugs before their respective Milestones. SAC ¶¶ 167; *see also* 168, 171. In electing to speak about where Bristol was in the Liso-cel approval process, asserting that *they personally* knew that Bristol was "on track" for Liso-cel to be approved prior to the Milestone deadline, and conceding that *they* were *personally* involved and "committed" to "timely approval" of Liso-cel before its Milestone deadline, Defendants either knew or were reckless in not informing themselves about the specifics of the FDA's approval process for Liso-cel, including the timing and substance of Bristol's FDA submissions and any FDA feedback thereto, which made clear that Bristol was neither "on track"

for nor "committed" to approval before the milestone deadline.[9] When an executive speaks on a particular subject, an inference can be drawn that that executive had or should have had knowledge of the information underlying the subject. *See, e.g.*, *In re Romeo Power Inc. Securities Litig.*, No. 21-CV-3362, 2022 WL 1806303, at *4–5 (S.D.N.Y. June 2, 2022) (imputing scienter where executives spoke about battery supply because of "the importance of battery cells and [the executives'] comments on supplies"); *Heller v. Goldin Restructuring Fund, L.P.*, 590 F. Supp. 2d 603, 622 (S.D.N.Y. 2008) (statement about one investor's commitment to a fund sufficient to impute scienter of the overall undercapitalization of the fund); *Van Dongen v. CNinsure Inc.*, 951 F. Supp. 2d 457, 472–73 (S.D.N.Y. 2013) (finding knowledge of undisclosed equity incentive compensation plan sufficiently pled based on defendants' omissions and denials about the plan, including public filings, press releases, presentations, and statement).[10]

Fifth, the significance of the Celgene merger to Bristol also supports an inference of scienter. *See* SAC ¶¶ 10-14; 91-94; 97; 105-120. Liso-cel was "one of the core reasons for Bristol's decision to acquire Celgene" and Bristol was intensely focused on the terms of the CVRs. SAC ¶¶ 106-14. Therefore, "[d]etermining the value of Liso-cel and Celgene's other pipeline drugs necessarily required extensive diligence by Bristol and the Individual Defendants regarding the likelihood of their approval by the FDA, the status of the regulatory approval process and the timetable by which the drugs were likely to be approved." SAC ¶ 19. In this District, such

[9] This is not a "circular argument." Order at 13 n.6. The Individual Defendants' statements imputed an obligation on them to be informed about the topics on which they were speaking. Thus, because Bristol's executives ***spoke*** about the Liso-cel approval process, this Court should reasonably infer that they ***knew*** about it, too. Further, the Individual Defendants' repeated statements illustrate how important the Liso-cel approval process was to Bristol, which also supports an inference that they were involved in and tracking its process.

[10] *See also Zak v. Chelsea Therapeutics Int'l, Ltd.*, 780 F.3d 597, 611 (4th Cir. 2015) (scienter inquiry necessarily involves consideration of "the context of the statements that a defendant affirmatively made").

circumstances are grounds for imputing scienter on executives or a corporation. *See In re XL Fleet Corp. Sec. Litig.*, No. 21-CV-2002, 2022 WL 493629, at *6 (S.D.N.Y. Feb. 17, 2022) (noting that acquiror's directors' "substantial[] involve[ment] in conducting due diligence [during merger] supports a finding of conscious misbehavior or recklessness as to those three individuals with respect to acquiree's inflated sales numbers).[11]

2. The Amended Complaint Adequately Alleges Corporate Scienter.

Bristol also had the requisite corporate scienter. Order at 16. Corporate scienter requires that a plaintiff "create a strong inference either (1) that someone whose intent could be imputed to [the company] acted with the requisite scienter or (2) that the [alleged misstatements] would have been approved by corporate officials sufficiently knowledgeable about [the company] to know that those statements were misleading.'" *Id.* The SAC satisfies that standard.

In addition to the allegations discussed above regarding Defendants Caforio and Hirawat and the impact of missing the Liso-cel deadline on Bristol's revenue, Bristol top executives spoke regularly on the Liso-cel approval, the Company created two different Committees whose responsibilities included keeping Bristol leadership apprised of the Liso-cel FDA approval

[11] The Court had two concerns with this argument. First, it noted that core operations allegations are "supplementary," not "independently sufficient means to plead scienter." Order at 14-15. But Plaintiffs do not rely solely on a core operations argument. Rather, the singular importance of the Celgene merger, and the integration of its therapies into Bristol's pipeline, is but one of many alleged facts supporting a conclusion that Defendants were well aware of how the Liso-cel approval process was going and that their statements were, therefore, false. Second, the Court observed that, in any event, "[w]hen applying the doctrine, courts have required that the operation in question constitute nearly all of a company's business before finding scienter." *Id.* at 15. The SAC meets this standard: by avoiding the $6.4 billion CVR payout, ***Bristol increased its net earnings in 2021 from $600 million to $7 billion***. SAC ¶ 206. In other words, nearly all of Bristol's business – ***91% of its annual net earnings*** – can be attributed to Bristol's successfully avoiding the CVR deadline. This raises it to the level of a "core operation." *See, e.g.*, *Saraf v. Ebix, Inc.*, __ F. Supp. 3d __, No. 21-CV-1589, 2022 WL 4622676, at *5 (S.D.N.Y. Sept. 30, 2022) (Furman, J.) (suggesting 91% of company revenue would satisfy core operations doctrine if shown to come from one source).

process, and dozens of Bristol's top regulatory personnel – numerous VPs of Cell Therapy and Directors of Quality Systems and Quality Assurance – regularly engaged with the FDA during the approval process. *See* SAC ¶¶ 5 n.2; 41, 46.[12] Such senior executive knowledge – specifically in the context of due diligence regarding a merger – is regularly imputed to the entire corporation. *See, e.g.*, *XL Fleet*, 2022 WL 493629, at *6 (imputing knowledge of sales information because non-defendant "had intimate knowledge of" sales information, "reported directly to [individual defendants]," and "worked directly" with individual defendants; imputing knowledge from individual defendants to corporation because defendants had "served successively as CEO of" corporate defendant). *See also In re: EZCorp, Inc. Sec. Litigations*, 181 F. Supp. 3d 197, 210 (S.D.N.Y. 2016) (plaintiff's allegations that the company's "executives had access to information on [certain] operating practices" that conflicted with public statements established corporate scienter) (quoting *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc.*, 531 F.3d 190, 195 (2d Cir. 2008)). This is true even if the knowledge is not in the minds of the individual defendants, but instead other senior executives. *See In re Marsh & McLennan Cos., Inc. Sec. Litig.*, 501 F. Supp. 2d 452, 481 (S.D.N.Y. 2006) (noting that courts "readily attribute[] scienter of management-level employees to corporat[ion]"); *In re Vale S.A. Sec. Litig.,* No. 15-CV-9539, 2017 WL 1102666, at *34 (S.D.N.Y. Mar. 23, 2017) ("officers and directors acting within the scope of their authority" can establish corporate scienter).[13]

[12] These include senior executives from Global Regulatory Sciences, Global Risk Management, and Global Development Operations, as well as Maria Brown, VP of Cell Therapy Development and Operations Quality, who was present at the closing meetings with the FDA. SAC ¶¶ 41, 46, 49 (referencing Jackie Elbonne, Chief Quality Officer and Senior VP of Global Quality, and Jocelyn Seymour, Senior VP of Global Regulatory Affairs who directly corresponded with the FDA about Liso-cel).

[13] Defendants cite *Jackson v. Abernathy* for the proposition that "this is not one of the 'exceedingly rare instances' where an alleged statement is 'so dramatic' that collective corporate scienter can

3. The Amended Complaint Adequately Alleges Motive and Opportunity.

The SAC sufficiently alleges that Defendants "benefitted in some concrete and personal way from the purported fraud." Order at 9. The Court previously found Plaintiffs placed much weight on the "massive" size of the alleged fraud, but that "the size of the fraud alone does not create an inference of scienter." *Id.* Plaintiffs in the SAC do not rely "solely" on the size of Bristol's alleged fraud to establish motive and opportunity. In addition to the size of the fraud, Plaintiffs allege the enterprise-level importance of the Celgene merger; the importance of the incorporation of Celgene's therapies, including Liso-cel, on the success of the merger; the extraordinary press attention Liso-cel and the merger received; the recent underperformance in Bristol's stock and the slew of criticisms that had recently been levied against Defendant CEO Caforio and the rest of Bristol's leadership, and the recognition that the Celgene merger was seen as an opportunity to reverse that trend. SAC ¶¶ 10-14, 19, 92-94, 105-114, 116-120, 173, 206.[14]

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be inferred." DB 31 (quoting 960 F.3d 94, 99 (2d Cir. 2020)). But Defendants mischaracterize those phrases. The full sentence from *Jackson* reads: "But a shareholder need not always identify the individuals responsible for the fraudulent statement. In exceedingly rare instances, a statement may be so 'dramatic' that collective corporate scienter may be inferred." *Id.* at 98-99. The *Jackson* court was specifically analyzing the "rare instances" where plaintiffs are unable to identify which individuals were responsible for an allegedly fraudulent statement. That is not the case here, where each statement's author is identified in the SAC.

[14] Defendants argue they could not have been motivated to engage in the alleged fraud because "[a]ny deliberate effort to prevent timely FDA approval … would have exposed [Bristol] to potential liability[.]" DB 20. This non-sensical argument would immunize corporations from all allegations of securities fraud – or ***any*** type of corporate crime, for that matter – because any illegal corporate activity exposes the corporation to damages and costly legal fees. Defendants' cases stand for a different point entirely: that the plaintiff's theory of fraud in those cases "defie[d] economic reason." In *ECA, Loc. 134 IBEW Joint Pension Tr. of Chicago v. JP Morgan Chase Co.*, the court noted, "Plaintiffs 'fail to allege facts explaining why, if it was aware of Enron's problems, [JP Morgan] would have continued to lend Enron billions of dollars." 553 F.3d 187, 203 (2d Cir. 2009). In *In re AT&T/DirecTV Now Sec. Litig.*, the court rejected plaintiffs' core operations argument because it would "make no economic sense" for AT&T to pay "over $100

4. COVID-19 Did Not Cause Liso-Cel to Miss the Milestone Deadline

Defendants' attempt to refute Plaintiffs' strong allegations of scienter by blaming the COVID-19 pandemic for Liso-cel's delayed approval is belied by the facts. First, that Bristol would likely not obtain FDA approval for Liso-cel before the Milestone date was known by Defendants as early as December 18, 2019 – ***before the COVID-19 pandemic even began*** – as a result of Bristol's inexplicable failure to submit a proper CMC with its BLA. SAC ¶ 30-32. Compounding this obviously deficient filing, Bristol then unjustifiably and highly unusually waited three months before submitting the CMC portion of the BLA on April 15, 2020. SAC ¶ 27. Even more unexplainable, even though the CMC submission is "***the most important*** section of the BLA," Bristol submitted a wholly inadequate CMC which included only "summaries" of key tests, which the FDA promptly determined were "***inadequate to understand and assess control of the analytical procedures and respective validations.***" SAC ¶ 30. COVID-19 cannot explain these intentional delays or how one of the most sophisticated drug companies in the world made inexplicable errors in routine and critically important FDA submissions.

Then, because of that deficient filing, Bristol was forced to file an amendment. It waited twenty-three days from the time it was asked by the FDA to provide the missing data on assays and validation, until April 15, 2020, even though the data to be submitted was already readily available. Despite the onset of the COVID-19 pandemic, the FDA promptly determined – just 20 days later – on May 5, 2020, that the amendment constituted a Major Amendment and, as a result, the FDA was forced to move back its PDUFA date by ***three months***. SAC ¶ 32. Thus, almost immediately after the Celgene merger took place, and ***before*** COVID-19 had truly emerged,

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billion" to acquire the company … if it did not genuinely believe that DTVN would be a successful and profitable product." No. 19-CV-2892 (VEC), 2020 WL 4909718 (S.D.N.Y. Aug. 18, 2020).

Bristol's actions had delayed the approval of Liso-cel by far more than three months,[15] ***well beyond the thirty-six-day span by which Bristol missed the CVR deadline.***

Second, the FDA approved a number of directly analogous drugs in a timely fashion despite the onset of the COVID-19 pandemic. As the SAC alleges and the Court required, these analogous drugs are "apples-to-apples" comparators to Liso-cel. Order at 15-16.[16] Specifically, a former FDA expert who specialized in exactly such drug approvals demonstrates that, under an apples-to-apples comparison, the approval timeline for Liso-cel was a *statistical anomaly*, *even accounting for the complexity of its approval process and an unprecedented global pandemic.*[17] Notably, the aforementioned statistical analysis conducted by the FDA Biologics Expert *included*

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[15] Bristol waited a month to initially submit its CMC module and another three weeks to submit the proper data, and the Major Amendment that resulted delayed the FDA PDUFA date by 90 dates. SAC ¶¶ 27, 131, 138-40. These delays alone – setting aside the rescheduling and eventually failed inspections and the delays in the Form 483 responses – amount to ***142 days of delay***.

[16] According to the Expert, "to conduct an apples-to-apples comparison, one should consider *all the parenteral cell/gene therapy biologics*" that the FDA, CBER, and the Office of Tissues and Advanced Therapies (OTAT) approved during the pandemic, while Liso-cel was being considered, except for tissue and cord blood products, because they are not Advanced Therapies, and except for those manufactured abroad, because the FDA was not doing international inspections during the pandemic. SAC ¶ 52. According to the Expert, "[a]fter excluding those biologics, one is left with biologics directly comparable to Liso-cel, *because they all undergo identical approval processes with CBER and OTAT and were inspected by Team Biologics in-person and CBER virtually at the time, like Liso-cel[.]*" *Id.* (emphasis added).

[17] Defendants fail to meaningfully engage with the substance or implications of the above analysis. Instead, they cite one case from California and claim that empirical and statistical analysis "is not a basis to infer scienter for defendants in this case." DB at 22 (citing *In re Hansen Natural Corp. Sec. Litig.*, 527 F. Supp. 2d 1142, 1155-56 (C.D. Cal. 2007). But *Hansen* is irrelevant. There, the statistical analysis at issue, which attempted to show defendants had engaged in illegal backdating of stock option grants, was conducted ***by the plaintiff*** and constituted the ***entirety*** of the evidence supporting scienter. Here, by contrast, the analysis at issue, conducted by an industry expert, is just one of numerous allegations supporting an inference of scienter, and provides clear explanation for how it was conducted and which data it used. *See also Set Cap.*, 996 F.3d at 73 n.21 (accepting data analysis regarding likelihood of market volatility alleged in complaint); *Myun-Uk Choi v. Tower Rsch. Cap. LLC*, 890 F.3d 60, 64 (2d Cir. 2018) (accepting plaintiffs' statistical argument that it was a "near statistical certainty" that at least one defendant trader traded with one plaintiff).

non-priority review biologics, meaning it "actually overestimated the approval time for Liso-cel comparators." SAC ¶ 52. That is, while the Expert could have justifiably only compared Liso-cel to other priority review projects, out of an abundance of caution – and specifically to address the Court's concerns – the Expert declined to do so, and instead compared Liso-cel to ***all*** comparable drug therapies, regardless of whether they were receiving priority review or not. *Thus, even when comparing the approval timeline to therapies that the FDA explicitly considered lower priority, Liso-cel took a statistically anomalously long time to be approved.*[18]

Other allegations further confirm that the delays in the approval of Liso-cel cannot be explained away by COVID-19. For example, Bristol failed to prepare its facilities for inspection for reasons "wholly unrelated to the global pandemic," such as preventing mold and using the right kind of disinfectants. SAC ¶ 195. Similarly, CW #10, an executive in the quality department of Celgene/Bristol, made clear that Bristol "cannot blame the delay of approval of Liso-cel on COVID-19 alone." SAC ¶ 194. Analysts concurred. For example, Mizuho analyst Salim Syed noted that Bristol was likely not "entirely thorough" in its BLA applications – a misstep that has nothing to do with COVID-19 – and that, therefore, COVID-19 could not be "the whole story" with respect to Bristol's missing the CVR deadline. SAC ¶ 193.[19]

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[18] This Court previously held that "how the FDA handled other approvals during the pandemic has no bearing on Defendants' actions and knowledge" because "Defendants did not determine the FDA's priorities and how it should deploy its resources during the pandemic" (Order at 16), but that is exactly the point Plaintiffs and the Expert are making. The FDA operated within a general range of efficiency during the pandemic. The only reason the FDA approval process was statistically longer for Liso-cel was because of ***Defendants'*** repeated failures, not some unidentified FDA delay. It was Defendants' failure to file an adequate CMC submission and failure to quickly remedy that error that caused the delay, ***not*** any FDA delay.

[19] This Court noted in its prior opinion that "the FDA did approve Liso-cel during the pandemic and only a few weeks after its target approval date," Order at 15, but that ***supports*** Plaintiffs' theory of this case, which is that Bristol intentionally or recklessly delayed the approval of Liso-cel ***just enough*** to avoid paying out investors while maximizing profits to Bristol from its subsequent sales

5. Unintentional Mismanagement Did Not Cause Liso-Cel to Miss the Milestone Deadline

The Court previously concluded that, based on the original complaint, "the Liso-cel setbacks are more attributable to ... 'mismanagement.'" That is not the case with Plaintiffs' SAC. Rather, as the FDA Biologics Expert repeatedly noted, and numerous confidential witnesses confirmed, Defendants' deluge of failures are far too obvious, unusual, and atypical for a company of Bristol's experience to be attributed to mere unintentional mismanagement. *See, e.g.*, SAC ¶ 27 (delay in filing CMC "unjustifiable and highly unusual"); SAC ¶ 49 (accidentally submitting a woefully deficient CMC is "implausible"); SAC ¶ 52 ("Bristol's eleven-month approval timeline for Liso-cel is a statistical anomaly when weighed against … comparators."); SAC ¶ 138 (twenty-three day delay in submitting amendment was "highly unusual"); SAC ¶¶ 59-60, 148-49 (inspection deficiencies were "unusual and avoidable" and violations were "glaring"); SAC ¶ 151 (Form 483 response was "obviously inadequate"); SAC ¶ 152 (two-month gap between the inspection and the final Form 483 response is "unheard of"); SAC ¶ 153 (sending inexperience staff member to prepare facility for inspection was "shocking"). Moreover, even claims involving mismanagement are properly brought under Section 10(b) when the statements made by a company and/or its executives about issues concerning the management of its product or business operations are false or misleading. *See, e.g.*, *Karimi v. Deutsche Bank Aktiengesellschaft*, 607 F. Supp. 3d 381, 396 (S.D.N.Y. 2022) ("[t]he federal securities laws prohibit misrepresentation of material facts, even when those material facts relate to corporate mismanagement"); *City of Sterling Heights Police & Fire Ret. Sys. v. Abbey Nat., PLC*, 423 F. Supp. 2d 348, 355 (S.D.N.Y. 2006) (same); *In re NTL, Inc. Sec. Litig.*, 347 F. Supp. 2d 15, 27 (S.D.N.Y. 2004) ("a failure to

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of Liso-cel. *See, e.g.*, SAC ¶¶ 3; 7; 53; 185.

disclose facts that amount to mismanagement may render other statements misleading"). Here, Plaintiffs have plainly alleged an element of deception: despite their repeated comments on the FDA approval process of Liso-cel, Bristol never notified the public that the delays were the result of its own, avoidable misconduct, that it was not using "diligent efforts" to obtain timely approval, and that it was highly unlikely it would obtain approval before the deadline.

6. Defendants Misstate the Facts and Law Regarding Scienter

Defendants argue Plaintiffs' substantial scienter allegations do not "shed light" on what Defendants Caforio and Hirawat actually knew or when they knew it. DB at 21. This characterization is wrong on the facts and the law. First, on the facts, as laid out above, there is sufficient circumstantial evidence[20] to support the inference that both Caforio and Hirawat were aware of Bristol's repeated missteps regarding the Liso-cel approval process. They spoke repeatedly on the subject; they received FDA correspondence on the approval process; Caforio served on a Committee tasked with monitoring and providing updates regarding the integration and production of Celgene's therapies like Liso-cel; and multiple Bristol employees and an expert with intimate knowledge of the FDA approval process attested that the top executives of Bristol received regular updates regarding the process of the Liso-cel approval application.

Second, on the law, Defendants improperly assert Plaintiffs must offer direct evidence at this stage of litigation, but all that is required is that Plaintiffs put forth enough evidence to make plausible the inference that Defendants knew about the FDA-related failures. *See supra* at 6.

B. Defendants' Statements are False and Misleading and Omit Material Information

Defendants argue that "Plaintiffs also have failed to plausibly allege that any challenged

[20] CW #9's allegations also constitute *direct* evidence of Bristol's scienter. *See* SAC ¶¶ 47, 177.

statement was false 'at the time it was made.'" DB 3 (emphasis removed).[21] Defendants' argument fails under Plaintiffs' theory of this case, which is that Defendants knew or were reckless in not knowing that the Company's repeated and highly unusual FDA submission failures resulted in the delay of Liso-cel's FDA approval.

In arguing that Plaintiffs fail to allege falsity in the offered misrepresentations, Defendants engage in sleight of hand by drawing the Court's focus to particular portions of a misrepresentation that were technically true – *e.g.,* that Bristol *did* complete its Liso-cel BLA by December 18, 2019, *see* DB 12 (referencing Statements 1-3)[22] – while ignoring the statement as a whole, and the purpose for which it was offered – *i.e.*, to ease concerns regarding the CVR deadline for Liso-cel. When reviewing the statements as a whole, they are false and misleading because each failed to disclose to investors Defendants' knowledge of the FDA submission and inspection failures that would likely result in the Company's not meeting the CVR deadline.[23] This point applies equally to Plaintiffs' four newly alleged misstatements – Statements 2, 15, 16, and 17.[24]

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[21] This argument, which the Court did not credit, also appears in Defendants' original motion. ECF No. 100 at 16-17; 19.

[22] Plaintiffs herein adopt the statement numbering convention used in Defendants' Appendix 1.

[23] For example, in Statement 3, Bristol announced the submission of its BLA, but did not disclose that it had waited an unnecessary twenty-nine days to do so, or its knowledge that the submission was wholly inadequate. In Statement 5, Bristol stated that, following the Major Amendment determination, the Company would "work closely with the FDA" to support the approval of Liso-cel, but omitted that the Company easily could have avoided the Major Amendment designation altogether but for its unexplainable submission failures.

[24] In Statement 2, Bristol stated that it was on track to submit Liso-cel by the end of the year, but did not disclose that Bristol's actions would likely, if not definitively, cause Liso-cel to miss meeting the CVR deadline. In Statement 15, Bristol stated that it was continuing to work with the FDA, but declined to mention the company was submitting inadequate and delayed information to the agency. In Statement 16, Bristol reassured investors that it was on track to meet its regulatory approval goals, without disclosing its conduct of taking unusual missteps so to avoid meeting the CVR deadline. Finally, in Statement 17, Defendants told investors that the FDA had granted priority review of Liso-cel, but did not disclose that Bristol planned to erect numerous obstacles to likely or definitely prevent the drug from being approved by the CVR deadline.

Moreover, ***even if*** Defendants had not developed a secret plan to deliberately miss the CVR deadline – which they did – they would still be liable, because each of the alleged misstatements failed to disclose Bristol's utter recklessness, at best, with respect to getting Liso-cel approved on time. By concealing, repeatedly, the central role Bristol played in delaying the approval of Liso-cel, Bristol defrauded the market from being able to accurately value the CVRs.

1. The Misstatements are Not "Opinions"

As Plaintiffs previously argued, these misstatements are not opinions because Defendants knew and failed to disclose that Liso-cel would not launch by year-end 2020, and that there was a 0% chance the CVRs would pay out because Defendants were deliberately slow-rolling the Liso-cel approval process so as to miss the Milestone deadline. ECF No. 105 at 30-31.[25] But, even assuming these statements were opinions – and they are not – they are actionable under *Omnicare* because they did not "fairly align[] with the information in [Defendants'] possession at the time," *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 188-89 (2015).[26] That is, Defendants' characterizations of the likelihood of missing the Milestone date need only not "fairly align" with the information they had at the time. That is certainly true here.

2. Safe Harbor

Defendants re-raise their argument that Plaintiffs' alleged misstatements fall under the safe harbor provision of the PSLRA because they are forward-looking statements or because they are accompanied by sufficiently cautionary language. In both instances – as indicated by the fact that

[25] Defendants raised this argument, which the Court did not embrace, previously. *See* ECF No. 100 at 17-18.

[26] *Omnicare*'s recognition that an opinion statement is false even if not subjectively disbelieved "altered the standard" in the Second Circuit, which previously required that an opinion statement "was both objectively false and disbelieved by the defendant at the time it was expressed." *Tongue v. Sanofi*, 816 F.3d 199, 209 (2d Cir. 2016).

the Court agreed with Defendants regarding safe harbor and alleged misrepresentations in the Merger Proxy Statement, but not the other alleged misrepresentations – Defendants are wrong.

a. The Misrepresentations are Not Forward-Looking Statements

The alleged false statements are not forward-looking because they relate to then-existing facts and conditions. Forward-looking statements are those "whose truth cannot be ascertained until sometime after the time they are made[.]" *In re Aegon N.V. Sec. Litig.*, No. 03-CV-0603, 2004 WL 1415973, at *12 (S.D.N.Y. June 23, 2004). But the falsity of the misstatements here was known when uttered: Defendants knew that the expected value of the CVRs issued was ***$0*** because Defendants had delayed the FDA approval process long enough to miss the Milestone deadline, rendering the CVRs worthless. As Plaintiffs allege, ***at the time of each alleged misstatement***, Defendants had already intentionally or recklessly delayed FDA approval of Liso-cel.[27]

b. There Was No Cautionary Language to Immunize Defendants

Defendants' misstatements were not accompanied by meaningful cautionary language either. Accompanying language is not meaningfully cautionary "if a reasonable investor could have been misled into thinking that the risk that materialized and resulted in his loss did not actually exist." *In re Delcath Sys., Inc. Sec. Litig.*, 36 F. Supp. 3d 320, 333 (S.D.N.Y. 2014). Defendants offer a long list of instances of purportedly meaningful cautionary language, but none of them indicate Defendants planned to deliberately delay the FDA application process, nor do they convey that the then-actual value of the CVRs was $0. Rather, in each example of supposedly cautionary language, Defendants

[27] Defendants' cited cases require no different outcome. In *In re Sanofi Sec. Litig.*, plaintiffs only alleged the comments about FDA approval were misleading because they failed to include "the concerns the FDA had expressed about the trials or Lemtrada's approval prospects." 87 F. Supp. 3d 510, 531 (S.D.N.Y. 2015). Here, by contrast, the missing of the Milestone date could have been avoided if not for Defendants' conduct. And, unlike in *In re Nielsen Holdings PLC Sec. Litig.*, Defendants here "did not believe their projections when they were made" because they knew the CVR deadline would be missed. 510 F. Supp. 3d 217, 231 (S.D.N.Y. 2021).

actually ***further misled*** investors into thinking the CVRs remained valuable. *See, e.g.*, DB 17 (the CVRs "ultimately ***may*** have no value"; "***If*** the CVR milestone . . . is not achieved for any reason . . .") (emphasis added). Moreover, these statements are boilerplate warnings of general risk factors, rather than the "specific cautionary statements" required by the Safe Harbor provision. *See Delcath*, 36 F. Supp. 3d at 334; *In re MannKind Sec. Actions*, 835 F. Supp. 2d 797, 817 (C.D. Cal. 2011); *In re BioMarin Pharm. Inc. Sec. Litig*, No. 3:20-CV-06719, 2022 WL 164299, at *8 (N.D. Cal. Jan. 6, 2022) (statement that "COVID-19 could postpone necessary interactions with regulators" and "delay review or approval" was insufficiently cautionary because it was not tailored to alleged misrepresentations regarding likelihood of approval by target date).

C. Loss Causation is Sufficiently Alleged

Under Rule 8, only two conditions must be satisfied for loss causation to be sufficiently alleged: (1) that "the loss be foreseeable"; and (2) that "the loss be caused by the materialization of the concealed risk." *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 173 (2d Cir. 2005). The former is satisfied if "the risk that caused the loss was within the zone of risk ***concealed*** by the [alleged] misrepresentations and omissions." *Id.* The latter is satisfied if "the misstatement or omission concealed something from the market that, when disclosed, negatively affected the value of the security." *Id.* Plaintiffs have satisfied both inquiries. First, the risk that caused Plaintiffs' loss was Defendants' failure to obtain FDA approval of Liso-cel prior to the CVR deadline. This risk is squarely within the "zone of risk" concealed by Defendants—namely by their failure to disclose a plan to slow-roll FDA approval and their misstatements about acting with diligence. SAC ¶ 135.[28]

[28] *See, e.g.*, *In re Bristol Myers Squibb Co. Sec. Litig.*, 586 F. Supp. 2d 148, 163-66 (S.D.N.Y. 2008) (loss causation adequately pled where announcement of criminal investigation "was not an isolated event in itself, [but] was instead the 'tip of the iceberg'—the first in a series of revelations which would ultimately expose the Company's entire fraudulent scheme"); *In re Initial Pub. Offering Sec. Litig.*, 544 F. Supp. 2d 277, 299 (S.D.N.Y. 2008) (loss causation adequately pled because misrepresentations "concealed the alleged market manipulation that caused plaintiffs'

Second, these misrepresentations negatively affected the value of the CVRs. Most plainly, the disclosure of the fruits of Defendants' plan to slow-roll the FDA approval of Liso-cel resulted in a decline in the CVRs' value until it reached $0. SAC ¶ 185.[29]

D. Defendants Are Controlling Persons

Plaintiffs have pled primary violations of the Exchange Act and that the Individual Defendants culpably participated in those violations, SAC ¶¶ 256–61, thus adequately pleading controlling person claims. *See, e.g.*, *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 108 (2d Cir. 2007).

CONCLUSION

For the foregoing reasons, Defendants' motion should be denied.[30]

losses[,]" and without them "plaintiffs' losses would not have occurred[, and] plaintiffs' losses are those that could be expected to result from the concealment of the market manipulation scheme").

[29] On May 6, 2020, the CVR price declined by 15% from the prior day, from $4.43 to $3.75 per share, in response to Bristol's press announcement that the FDA target approval date for Liso-cel had been pushed back from August 17 to November 16, 2020. SAC ¶ 244. The CVR price fell another 15% on September 8, 2020, following Bristol's disclosure that the Lonza facility would require an inspection and that neither of the two required plant inspections had occurred yet. SAC ¶ 298. The CVR price plummeted 64% on November 5, 2020, due to statements in Bristol's Form 10-Q revealing only one facility had been inspected and the other facility's inspection had not even been scheduled. SAC ¶ 299. The CVR price fell 43% on November 16, 2020, upon Bristol's announcement that Lonza facility inspection had been further delayed. SAC ¶ 300.

[30] If the Court grants Defendants' motion to dismiss, it should again do so with leave for Plaintiffs to amend the Complaint, as Plaintiffs have several outstanding FOIA requests not fulfilled within the short 28-day period Plaintiffs had to amend. Plaintiffs expect these requests to be fulfilled within weeks and thus would have additional information to further supplement their pleadings.

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Respectfully Submitted,

By: */s/ Steven J. Toll*

COHEN MILSTEIN SELLERS & TOLL PLLC
Michael B. Eisenkraft
Laura H. Posner
Benjamin F. Jackson
88 Pine Street
14th Floor
New York, NY 10005
Tel. (212) 838-7797
meisenkraft@cohenmilstein.com
lposner@cohenmilstein.com
bjackson@cohenmilstein.com

Steven J. Toll (*pro hac vice*)
Brendan Schneiderman (*pro hac vice*)
1100 New York Avenue, N.W
East Tower, STE. 500
Washington, DC 20005
Tel. (202) 408-4600
stoll@cohenmilstein.com
bschneiderman@cohenmilstein.com

Lead Counsel for Lead Plaintiff, Ehab Khalil, and the Proposed Class

BRONSTEIN, GEWIRTZ & GROSSMAN, LLC
Peretz Bronstein
Eitan Kimelman
60 East 42nd Street, Suite 4600
New York, NY 10165
Tel. (212) 697-6484
peretz@bgandg.com

Counsel for Ehab Khalil

ENTWISTLE & CAPPUCCI LLP
Robert N. Cappucci
Brendan J. Brodeur
230 Park Avenue, 3rd Floor
New York, New York 10169
Tel. (212) 894-7200
rcappucci@entwistle-law.com

bbrodeur@entwistle-law.com

Andrew J. Entwistle
500 West 2nd Street, Suite 1900
Austin, TX 78701
Tel. (512) 710-5960
aentwistle@entwistle-law.com

Counsel for Plaintiffs SM Merger/Arbitrage, L.P., SM Investors, L.P. and SM Investors II, L.P.